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EXAMINING THE IMPLEMENTATION OF THE FOOD SAFETY MODERNIZATION ACT

WEDNESDAY, FEBRUARY 5, 2014

House of Representatives,

Subcommittee on Health

Committee on Energy and Commerce

Washington, D.C.

The subcommittee met, pursuant to call, at 10:00 a.m., in Room 2322 of the Rayburn House Office Building, Hon. Joe Pitts [Chairman of the Subcommittee] presiding.

Present: Representatives Pitts, Burgess, Shimkus, Murphy, Blackburn, Gingrey, Lance, Guthrie, Griffith, Bilirakis, Ellmers, Walden, Barton, Upton (ex officio),

Pallone, Dingell, Capps, Matheson, Green, Butterfield, Barrow, Christensen, and Waxman (ex officio).

Staff present: Matt Bravo, Professional Staff Member; Noelle Clemente, Press Secretary; Brad Grantz, Policy Coordinator, Oversight and Investigations; Sydne Harwick, Legislative Clerk; Carly McWilliams, Professional Staff Member, Health; Chris Sarley, Policy Coordinator, Environment and Economy; John Stone, Counsel, Health; Ziky Ababiya, Staff Assistant; Eric Flamm, FDA Detailee; Elizabeth Letter, Assistant Press Secretary; and Karen Nelson, Deputy Committee Staff Director for Health.

Mr. {Pitts.} The Chair will recognize himself for an opening statement.

According to the Centers for Disease Control, 48 million Americans, or one in six, will become ill from a foodborne disease each year. One hundred and twenty-eight thousand people will require hospitalization, and 3,000 will lose their lives as a result. Sadly, many of these diseases and deaths could have been prevented if proper safety precautions had taken place on the farm, in processing facilities, and while transporting foods.

The Food Safety Modernization Act (FSMA), the most far-reaching reform of the Food and Drug Administration's food safety authority since the 1930s, was signed into law in January 2011. The law tasked FDA with issuing major regulations covering such topics as preventative controls for human food and animal feed, produce safety, foreign supplier verification, accreditation of third-party auditors, intentional adulteration, and sanitary transportation, among others.

I am particularly interested in the sanitary

transportation proposal released last Friday. Since mid-2011, I have been following stories about commercial food trucks without proper refrigeration carrying perishable foods along our Nation's highways at dangerously high temperatures, and a subsequent investigation by the Indiana State Police. Perhaps Deputy Commissioner Taylor can speak to how the proposed rule would address situations like this.

I would like to commend Mr. Taylor for his outreach efforts and dialogue with all parts of the food supply chain prior to the release of these proposed rules and also for extending comment periods on issues unique to certain sectors of the industry, such as farmers. This conversation must continue.

I believe the success of FSMA's implementation will rest on a flexible regulatory structure that, one, encourages an efficient, risk-based approach to food safety, and two, acknowledges that a one-size-fits-all, overly burdensome model simply will not fit such a vast and diverse food supply chain such as ours.

In issuing its proposed regulations, FDA has released compliance cost estimates that differ significantly with

outside estimates, and I would be interested in learning about the assumptions and methodology the agency used to arrive at these figures.

Additionally, over the last few years, many parts of the food industry have voluntarily made progress toward preventing foodborne illness, and I would hope FDA would not punish these good actors as it seeks to bring the rest of the industry up to standard.

I would also ask Mr. Taylor for a commitment to work with industry, particularly with respect to inspections, after the final regulations go into effect. A collaborative, rather than adversarial, relationship with industry will yield greater compliance and ultimately further our goal of making the U.S. food supply the safest it can be.

Finally, while we need to finalize FSMA's regulations in a timely manner, I am concerned by the court-ordered deadline of June 30, 2015. These regulations are too important to be rushed through without proper thought and consideration.

I would like to welcome Mr. Taylor and thank him for appearing before us today. I look forward to his testimony.

[The prepared statement of Mr. Pitts follows:]

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Mr. {Pitts.} At this time I will yield the remainder of my time to Ms. Blackburn.

Mrs. {Blackburn.} And we do welcome you and are pleased that you are here. Thank you so much for taking the time to be here and for giving us the opportunity to talk with you and look at the FSMA and a look at food safety and the FDA and the responsibilities that exist by regulations, the guidance documents that affect the wide array of individuals and industries that are associated with our Nation's food supply. Everyone wants a secure food supply, and they don't want it to be burdensome and cumbersome and difficult, and they want some certainty in the process.

Since January 2013, the agency has issued a number of proposed rules and received a significant amount and number of comments. We hope we have the opportunity to review some of this with you today and look forward to making certain that we are all moving in the right direction for food security.

I yield back.

[The prepared statement of Mrs. Blackburn follows:]

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Mr. {Pitts.} The Chair thanks the gentlelady and now recognize the ranking member, Mr. Pallone, for 5 minutes.

Mr. {Pallone.} Thank you, Chairman Pitts, and thank you, Mr. Taylor, for being here today.

I appreciate the opportunity to check in with the Food and Drug Administration on its implementation of the FDA Food Safety Modernization Act, or FSMA. With the passage of FSMA 3 years ago, Congress gave FDA new tools to shift the food safety system from one that reacts and responds to food safety incidents to one that prevents them.

FSMA provided the first major overhaul of federal food safety laws since the 1930s, and it was enacted at a time when the public health challenges of an evolving domestic and global food supply chain were evident in a series of foodborne illness outbreaks and contamination incidents, and I am proud to have worked with my colleagues, Mr. Dingell and Mr. Waxman and Ms. DeGette, on food safety legislation that emphasizes a prevention and risk-based approach to food safety from farm to table, both for domestic and imported food, and ultimately to have supported the passage of FSMA.

Food safety is and should be a bipartisan issue, and I hope we in this committee will continue to do what we can to support progress in the modernization of our food safety system.

We have seen in the last year the rollout of many significant parts of the law including proposed rules for major framework elements such as produce safety standards, preventive controls and oversight of food imports. I appreciate the work FDA has done in engaging with stakeholders and incorporating public input into the development of these proposed rules. However, I continue to urge FDA to enact final FSMA rules as expeditiously as possible because the safety of U.S. consumers' food supply should not be put at risk.

In addition, the passage of FSMA did not end our work on protecting the public health from foodborne threats. There are 48 million Americans every year who get sick from foodborne illnesses, as estimated by the Centers for Disease Control and Prevention, and there are still several thousand deaths each year attributed to foodborne disease.

In order to ensure that the safety benefits of FSMA will

be fully realized, Congress must provide adequate resources to the FDA for implementation. The Congressional Budget Office estimated that the law could require $1.4 billion over 5 years to roll out, but the agency has received only a fraction of that in resource increases, not to mention the impacts of sequester.

The food import user fee and food facility registration and inspection user fee proposed in the President's budget could also substantially support the implementation of the modern effect of food safety system envisioned in FSMA. I support the idea of utilizing such food-related user fees, which I believe can benefit both industry and government by reducing foodborne illnesses and the associated costs, which can be significant. The estimated overall economic total of outbreaks is almost $80 billion annually.

With the health and safety of the American public at risk, we can't leave the job only half done by not adequately funding FDA to fully implement this important law.

And again, thank you, Mr. Chairman, and I yield back.

[The prepared statement of Mr. Pallone follows:]

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Mr. {Pitts.} The Chair thanks the gentleman and now recognizes the vice chairman of the subcommittee, Dr. Burgess, 5 minutes for an opening statement.

Dr. {Burgess.} Well, thank you, Mr. Chairman, and I appreciate, Mr. Taylor, you being here with us this morning and your willingness to discuss the implementation of the Food Safety Modernization Act and the shifting focus of food safety from reaction to prevention.

I must say, I am concerned that some of the rhetoric and initial goals for the process have not been matched by the proposed rules that have been released. The Food and Drug Administration did have substantial interaction with stakeholders initially but it seems that the rulemaking process was only prompted to completion by actions in the courts. Therefore, I am concerned that stakeholder comments were not adequately addressed in the proposed rulemaking. We should encourage the Food and Drug Administration to implement the Food Safety Modernization Act through a scientific and risk-based approach that addresses the needs and concerns of the companies that the laws affect.

Many companies and industries in the food supply system have been proactive and have implemented innovative methodologies to address the changing landscape of the food supply system. Companies should continue to identify microbiological and chemical hazards and implement preventive controls to effectively mitigate risk. We should promote an environment that encourages innovation and moves away from a one-size-fits-all regulation. And let me just say, as we sit here now over 3 years since the Food Safety Modernization Act was signed into law, I think it is significant that we are having this meeting, this hearing in February of this year.

Look, we all know what is going to happen when the weather heats up. We are going to have an outbreak. I don't know of what. I don't know where it will occur. But you have seen it, I have seen it through several years on this committee. We will be talking about salmonella, we will be talking about E. coli. I would like to know what is going to be different this year than has happened in previous years. What are you doing proactively with the new tools you have in the Food Safety Modernization Act that are going to allow us to perhaps predict and prevent but at least mitigate the

damage from these outbreaks that we all know will occur. And Mr. Pallone talked about the fact that the Food Safety Modernization Act was necessary, the first time it had been undertaken in decades. It was necessary because of the evolving nature of the global risk that was presented to our food supply, and as a consequence we both know that that evolving of the global risk has not changed. It has not diminished since the signing into law of the Food Safety Modernization Act. So if anything, it is even more critical this February than it was five Februarys ago or 10 Februarys ago. Our food supply system varies greatly across the United States. Certainly, a one-size-fits-all approach cannot address the needs of U.S. food suppliers effectively. I hope we can continue to work with your agency and the stakeholders to ensure that the food supply system has the flexibility needed to allow the industry to tailor their programs to their unique product needs while also ensuring the highest food safety benefits for all consumers.

Thank you, Mr. Chairman, for the recognition. I will yield back to you.

[The prepared statement of Dr. Burgess follows:]

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Mr. {Pitts.} The Chair thanks the gentleman and now recognize the ranking member of the full committee, Mr. Waxman, for 5 minutes for an opening statement.

Mr. {Waxman.} Thank you very much, Mr. Chairman.

In December 2010, Congress passed the most significant overhaul of FDA's oversight of food safety since passage of the Food, Drug, and Cosmetic Act in 1938. The FDA Food Safety Modernization Act, FSMA, we call it, represents a fundamental shift in how FDA approaches food safety, focusing on prevention instead of reaction.

It requires food facilities to develop procedures to prevent food contamination and to take corrective actions when contamination is discovered. It requires FDA to establish standards for the safe production and harvesting of fruits and vegetables. It mandates increased FDA inspections for both domestic and foreign facilities and gives FDA access to records relating to food safety. It gives FDA mandatory recall authority and improves its ability to detain unsafe food, and it gives FDA better tools to oversee the safety of imports. It encourages FDA to work with other federal,

state, local, and foreign agencies to more efficiently achieve food safety goals.

It is an ambitious law, even just on an administrative level. It requires FDA to prepare more than 50 regulations, guidances, reports, and studies in a short timeframe. Already, FDA has published proposed versions of the seven most important regulations. Given their complexity, their need to fit together and complement each other, and the breadth of their reach, these regulations were not easy to develop. Their release is an accomplishment for which FDA should be proud.

But now, of course, FDA must finalize them. I recognize the political pressure put on the agency to delay and re-propose. I also recognize the importance of ensuring that the regulations are workable and that they appropriately address the wide range of activities that they cover. But American consumers need FDA to act without further delay.

We all have heard the statistics. According to the Centers for Disease Control, every year 48 million Americans get sick, 128,000 are hospitalized, and 3,000 die from foodborne diseases. The goal of the law is to substantially

lower those numbers. American consumers will not get its full benefits until the rules are all finalized, and that is why FDA needs to finalize them as quickly as the agency can.

Mr. Chairman, I thank you for holding this hearing. It will be good to get an update from FDA on how the implementation of this extensive legislation is going. I hope FDA will also share with us the impact the current lack of user fees is having, or is likely to have, on its ability to fully implement the law and protect public health. I would prefer that we fully fund FDA through appropriations. However in today's political environment, that is not going to happen.

Enhancing food safety is in everyone's interest, Republicans and Democrats, consumers, farmers, and manufacturers. We should be doing everything we can to give FDA the resources it needs to make full use of its new authorities under the Food Safety Modernization Act.

Mr. Chairman, I look forward to the testimony. I want to apologize in advance. There is another subcommittee meeting simultaneously with this one, and I may not be here for the full opportunity to hear the testimony. I will try

to get back for questions.

I yield back the balance of my time.

[The prepared statement of Mr. Waxman follows:]

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Mr. {Pitts.} The Chair thanks the gentleman.

On our panel today, we have Mr. Michael Taylor, Deputy Commissioner, Food and Veterinary Medicine, U.S. Food and Drug Administration. Thank you for coming. Your written testimony will be made part of the record. You will have 5 minutes to summarize.

At this time, the Chair recognizes Mr. Taylor for 5 minutes for an opening statement.

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^STATEMENT OF MICHAEL R. TAYLOR, J.D., DEPUTY COMMISSIONER FOR FOODS AND VETERINARY MEDICINE, FOOD AND DRUG ADMINISTRATION

} Mr. {Taylor.} Thank you very much, Mr. Chairman, and good morning, Chairman Pitts, Ranking Member Pallone and members of the subcommittee, and first thank you for convening this hearing and giving us an opportunity to discuss the implementation of the Food Safety Modernization Act.

As you know, food safety is a fundamental public health concern and it is a topic on which the public does have high expectations, and unfortunately, as many of you have noted already, too many Americans get sick every year, too many go to the hospital and too many die due to foodborne illness, and the costs are high, estimated as high as $77 billion just in the costs associated directly with foodborne illness.

We will never have a zero-risk food supply, Mr. Chairman, but as the statements have indicated, most foodborne illnesses are in fact preventable. By preventing

foodborne illness, we can improve public health, reduce medical costs and avoid costly disruptions of the food system, and with food imports having risen many-fold over the last 2 decades, we need a strategy that also addresses the complexities and challenges of food safety in today's global food system.

Fortunately, Mr. Chairman, FSMA provides us with that strategy. It is a risk-based prevention strategy that builds on what the food industry and food safety experts have learned works to prevent harmful contamination and reduce foodborne illness. FSMA recognize the primary responsibility and capability of those who produce food to make it safe. It calls on FDA to issue regulations aimed at ensuring practical steps are taken throughout the farm-to-table system, as you have indicated, addressing produce safety, processing facilities, transport, and so forth.

FSMA also provides FDA new inspection mandates and enforcement tools that we can use to help ensure high rates of compliance with FSMA's new standards, which is how we will achieve the food safety and economic benefits that motivated FSMA's enactment, getting high rates of compliance with the

rules once they are issued.

One of FSMA's most important themes and one that we at FDA take very much to heart is partnership. FSMA directs us to work with CDC to improve foodborne illness surveillance with the Departments of Agriculture and Homeland Security to help get our standards right, and very importantly, with our State, local, territorial, tribal and foreign government partners to support and oversee implementation of FSMA standards. In fact, the centerpiece of FSMA is the mandate to work with the States and our other partners to build a national integrated food safety system that will enable us to achieve our food safety goals more effectively and efficiently. We eagerly embrace these governmental partnerships in doing our work.

We also believe strongly in partnership with the food industry and our consumer stakeholders. Our partnership approach has been demonstrated so far by the extensive outreach we have done to all segments of the food safety community domestically and internationally, both before and after issuing the proposed rules that FSMA mandates. We have benefited enormously from innumerable public meetings, dialog

sessions and webinars with individual groups and dozens of farm and plant tours, where my colleagues and I have learned firsthand how food safety can be achieved on a practical basis across the great diversity of our food system. We are committed to sustaining this partnership and dialog approach throughout the implementation of FSMA.

As you know, Mr. Chairman, and as you have already acknowledged, we have issued seven major rulemaking proposals mandated by FSMA, and when they are final, they will provide the framework for systematically building in prevention measures across the food system, again, produce safety, preventive controls, the things that you have pointed out.

I would be happy to answer questions about any of these rules, of course, but I want to highlight just very briefly some points about the proposals on produce safety and preventive controls which we published in January of 2013.

As you know, the proposed rule on produce safety would require farms covered by the produce rule, and it is a targeted set of farms, to follow certain standards aimed at preventing microbiological contamination of fresh produce. The proposal on preventive controls would require facilities

to have a written plan in place to do modern preventive controls, have plans in place, verify that those controls are working. These proposals are grounded in practices that many in the food industry are already following, but as we seek to create a level playing field of standards through regulation, we fully anticipated that a number of challenging issues would arise, and that is why we have emphasized outreach and dialog and that is why we have received over 15,000 comments on the produce safety proposal and over 7,000 on preventive controls. As I say, we have learned a lot through this process. That is why in December we announced that we intend to publish and seek further comment on revised rule language regarding certain key provisions in the produce and preventive control rules on which our thinking has evolved. Through this process, we are confident that we can issue final rules that improve public health protections while minimizing undue burden on farmers and food processors.

We also recognize that FSMA will only be as effective as its on-ground implementation of the final rules after they are issued. Our implementation strategy includes partnering with other governments to ensure appropriate and efficient

oversight and compliance but also a concerted effort prior to enforcement to facilitate compliance through education, technical assistance and regulatory guidance.

Now, before closing, Mr. Chairman, I must note the importance of finding the resources that FDA will need to implement FSMA in a way that achieves its important food safety and economic goals and meets the expectations of our many stakeholders. We have adequate resources now to issue the required regulations and conduct the mandated number of domestic inspections, and we will continue efforts to make the best use of the resources we have, but simply put, we cannot achieve FDA's vision of a modern food safety system and a safer food supply without a significant increase in resources. Last May, Secretary Sebelius submitted to Congress a report outlining the resources needed to adequately implement FSMA including resources needed to retrain FDA and State inspectors, provide training and technical assistance to small- and medium-sized farmers and processors, build the federal-State partnership and, very importantly, implement the new import safety system mandated by Congress.

The import need is particularly acute, Mr. Chairman. We import 50 percent of our fresh fruit and 20 percent of our vegetables, and imported food shipments have increased from about 400,000 per year in the early 1990s to nearly 12 million today, but clearly, our resources have not kept up with this incredible expansion of food imports. The need to improve import oversight was demonstrated once again in 2013 by significant outbreaks of foodborne illness involving the hepatitis A virus linked to pomegranate seeds from Turkey and the cyclospora parasite linked to produce from Mexico. Congress was right in mandating a new import safety system, which is needed to protect consumers and provide a level playing field for U.S. producers and processors, but we cannot do what FSMA mandates without the resources it takes to build the new import system.

We are grateful, of course, for the resources we have been given through the 2014 appropriation process, which will be helpful in the near term, but I would also note that the President's 2014 budget request included proposal for authority to collect two fees that would also go a long way toward helping us meet our food safety obligations under FSMA

while also, we think, providing benefits for the affected industry and our State partners. One would address a registration fee for facilities that are registered with FDA. The second would be an import user fee, a minimal amount per entry that would provide resources to fulfill the food safety purpose of FSMA and also provide greater efficiency and predictability for importers. We look forward, of course, to working with you on those.

I want to close, Mr. Chairman, and I appreciate the indulgence in going over the time, by just saying how gratified my colleagues at FDA and I have been by the strong expressions of support we continue to receive for our industry and consumer stakeholders and from the members of this committee for moving forward in implementing FSMA. It is important to get it right, and it important to get it done, and an undertaking of this complexity, we know there will always be challenging issues but we are confident that this collaborative approach that we have taken, pursuing this approach, we can resolve issues in a way that is good for food safety and workable across our amazingly productive and diverse food system. I look forward to your questions, Mr.

Chairman.

[The prepared statement of Mr. Taylor follows:]

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Mr. {Pitts.} Thank you. I will begin the questioning and recognize myself for 5 minutes for that purpose.

Mr. Taylor, as I said in my opening statement, I have been waiting for FDA sanitary transportation rule for some time since we passed the Sanitary Food Transportation Act. I have continued to hear some real horror stories about drivers turning off their refrigerator units to cut cost, and I called on the agency to expedite its efforts to address these serious problems. Can you briefly comment on the agency's recent proposal and what it will do to ensure food is safely transported from its producer or manufacturer to our local retailers?

Mr. {Taylor.} Certainly, Mr. Chairman. We do consider the safe transport element of FSMA to be an important part of the farm-to-table prevention strategy. Our science tells us that this is not the highest risk part of the food system by any means. We have fairly limited experience in recent years with outbreaks associated with transport. There have been historically major outbreaks. The Schwan's ice cream outbreak in the 1990s made 220,000 people sick by virtue of

inadequate sanitizing of trucks. But the rule that we have proposed under the FSMA mandate will ensure that there is clarity of responsibility among those who are shipping product, that is, who have produced a product and are seeking to have it shipped to a customer, those who are actually transporting the product and those who are receiving it, clarity of responsibilities for ensuring that the right practices are taken across that transport part of the food system including where it is appropriate and necessary to protect the safety of food that refrigeration is maintained.

And so we have focused in on the core elements that we think are important in transport. We think we have got a practical system that will provide us clarity of responsibility. Again, many in the industry are already doing these things but we will fill in, I think, importantly this part of the farm-to-table system.

Mr. {Pitts.} Thank you. There are a number of unique issues related to the inspection of seafood processing facilities and imports from abroad. Can you please comment not he various programs FDA has in place to oversee our global seafood supply as well as recent improvements made to

these systems.

Mr. {Taylor.} Certainly, Mr. Chairman. Back in 1996, actually, FDA issued so-called HACCP regulations, essentially preventive control regulations for seafood processing facilities, both in the United States and overseas, for facilities shipping product to the United States, and this is the modern approach to preventive controls that FSMA has mandated for the entire food supply and that we are working to implement, and so we have a long history of implementing modern preventive controls for seafood. We do import 80 percent of our seafood, and so the oversight of imports is a crucial part of the system. The system includes responsibility for the importer to verify, have some verification from the foreign supplier that they are implementing modern preventive controls, but we also prioritize in our foreign inspection program seafood facilities because we do want to verify that these modern preventive controls are being implemented and we target facilities based upon information we know about where potential hazards might be.

We also have, under the existing law, the authority to

stop product when it comes into the country. This is a reactive system, and it is not the prevention system that will ultimately have when FSMA is implemented, but we have strong authority. We have used it frequently with respect to seafood to detain product from facilities or even from countries where we have repeated violations of issues like animal drug resides or other matters of concern from a food safety standpoint.

So we have a solid program. We will continue to work to improve it but it is based upon the modern principles that now FSMA is mandating comprehensively.

Mr. {Pitts.} Thank you. The committee appreciates the agency's efforts in this regard and is committing to ensuring that unnecessary and duplicative programs do not hamper such efforts. Provisions added to the Farm Bill at the last minute expanding the Department of Agriculture's catfish program would do just that. I agree with GAO and others that while doing nothing to improve safety, this program is a waste of taxpayer dollars and would increase compliance costs across the seafood industry.

Understanding the complexity of the issues involved and

the diversity of those impacted, I appreciate the agency's extension of comments, particularly with respect to the produce and preventive control rules. Can you comment on whether the court-ordered deadline to finalize these major rules has hindered your agency's ability to continue what I consider an essential dialog with the regulated community?

Mr. {Taylor.} Mr. Chairman, we don't feel that the deadlines have hindered that dialog. The deadlines are a challenge but we are organized and focusing our efforts to meet those deadlines. We believe we can do it. We think our ability to reopen the comment period for some comment on some of the key issues of concern will advance the process but we will have to be very efficient and work very hard to meet those deadlines but we are committed to doing it.

Mr. {Pitts.} The Chair thanks the gentleman and now recognizes the ranking member, Mr. Pallone, 5 minutes for questions.

Mr. {Pallone.} Thank you, Mr. Chairman, and I want to thank you, Mr. Taylor, for coming here today. I know that Congress gave FDA a big job to do when we passed FSMA, so I wanted to ask you to give us a sense of the scope and

diversity of the new responsibilities that FDA is directed to undertake in about a minute or so.

Mr. {Taylor.} Just from a practical matter, it is really about creating comprehensively a new system of prevention. It is a new food safety system beginning with what happens on farms where we have never regulated for produce safety before going all the way through processing and transport and then recognizing that we have to manage global supply chains, so it is an entirely new import oversight system. So it is a massive undertaking. If you just read the law and count up the deiliverables, as I think you indicated, it is a huge task and it is requiring us to mobilize everything we have got now and to figure out, you know, and be very clear about the resources that we will need to carry it forward to successful implementation.

Mr. {Pallone.} Thanks. I touched in my opening statement, I said that CDC estimates that 48 million Americans get sick, 128,000 are hospitalized and 3,000 die each year from foodborne illnesses, and these numbers show that this is a serious problem that can be devastating for families.

Let me ask you two questions. What are the impacts on consumers who contract a foodborne illness and how will FSMA benefit consumers and reduce the burden of foodborne illness?

Mr. {Taylor.} Mr. Chairman, some people think that foodborne illness is just an upset stomach, and many of those 58 million cases are transitory illnesses, but they do add up to a big public health burden in and of themselves, but many foodborne illnesses are devastating, lifetime damaging experiences. People lose organ function. People's lives are changed forever and incurring not only great suffering on their part but medical costs, and then 3,000 people die. So it is more than a transitory stomachache.

And again, the whole idea here is to build in the practical preventive measures that can stop E. coli and salmonella and other pathogens that can make people sick from getting into the food system and doing that in the most practical but systematic way possible, and by doing that, again, we are not going to eliminate foodborne illness but we can substantially reduce these illnesses and benefit consumers. These illnesses are largely preventable, and I think what people expect is that we do everything we

reasonably can to prevent them, and I think that FSMA is the mandate and the system to do that.

Mr. {Pallone.} Well, I am going to get into the resources issue because you mentioned that, and that is obviously very relevant.

FSMA gives FDA many new tools to use to improve the safety of the food supply. However, I am concerned that you will have a hard time making full use of them without added resources. The agency's report to Congress last April on domestic capacity building to implement FSMA mentions there is a gap in funding needed to fully implement the law and it briefly discussed how the authority to generate new user fee revenues would be used for food safety, and as you know, the food safety bill that the House passed in 2009 did include facility registration and importer fees to increase resources.

Would you just comment on what the food-related fees proposed in the President's fiscal year 2014 budget would be used for if Congress gave FDA the authority to collect them, and how would the absence of user fee revenue affect the agency's ability to continue to implement FSMA?

Mr. {Taylor.} So there are two fees, as I mentioned. One is a facility registration fee. Those resources would be focused on improving inspection and being sure that our inspection force is trained and prepared to work under the new modern preventive system, so training for inspectors would be a big part of that. Those resources could also be used to support the federal-State partnership. We think we can be more effectively working closely with State partners who already conduct some inspections for us. They need their own training and capacity building.

The import fee would really be the key to building the new import system. We are mandated to establish this foreign supplier verification program requirement but that puts us in the position, which we want to be in, of auditing complex supply chain management systems. We need a whole different training and orientation of a frontline workforce. We need staff to do that work in addition to actually checking product coming in at the port of entry, and then very importantly, Congress, I think, wisely mandates us to be much more present overseas, to work with foreign governments, to do more foreign inspections, to see that preventive measures

are being taken offshore. So it is really building that new import system that the import fee would be crucial for.

Mr. {Pallone.} All right. Thanks so much. I still have a few minutes.

The chairman mentioned the catfish, and I would like to know, has FDA found catfish to be a high-risk food and can you describe for us the system FDA has in place for fish and seafood safety and whether FDA has found that catfish pose unique or special risk warranting special oversight?

Mr. {Taylor.} Certainly, the reason we issued the HACCP rules, the preventive control rules for seafood, is because seafood, if not handled properly, can present concerns, but within the seafood universe, we actually think catfish is on the lower end of the spectrum of potential risk. It is not sold in a form that is ready to eat. Smoked product, for example, is more risky. It is not consumed raw, generally, and we don't have a history of outbreaks associated with catfish.

Mr. {Pallone.} All right. Thanks again.

Mr. {Pitts.} The Chair thanks the gentleman and now recognizes the gentleman from Illinois, Mr. Shimkus, 5

minutes for questions.

Mr. {Shimkus.} Thank you, Mr. Chairman, and welcome, Mr. Taylor.

So in the full committee and our various subcommittees, it is amazing how some things reoccur, so my discussion is going to be--I am going to use the term ``recycling'', but as we have found in other sectors, we force ink producers to throw away ink instead of bringing them back through the process because of rules and regulations. As we heard yesterday, we force electronic manufacturers to throw away their boards instead of recycling them because of rules and regulations.

So this is the first question. In the process of commodities that are already safe for human consumption that goes through the process in the front end, and let us just take barley that is going to go into production of adult beverage--beer. Then it goes through the process but then there is always obviously the remaining ingredients after the process has occurred. Many times that then is used in animal feed issues. Now, a concern is developing that if in this process then FDA then forces that end-use muck that has been

used in animal feed to then go through another inspection process to see if it is, you know, safe for the feed processing and animal feed, then you will do the same thing that we did with ink and the same thing we do with computer boards. We will then add an additional burden in disposal and then we will take away a commodity product for food processes. That is a concern. Can you speak to that?

Mr. {Taylor.} Sure, Mr. Shimkus. We are aware of this issue, and of course, we have proposed a preventive controls rule for human food facilities and a preventive control rule for animal feed and animal food facilities based on the same principles that the law lays out, but there are differences in the way in which human and animal feed need to be handled for safety purposes, so we have two separate rules. But they have to fit together and they have to work in a way that does not disrupt this practice. We are very aware of this relationship between human food and animal food production, and we don't see any reason from a food safety standpoint to disrupt that at all, and based on the comments that we are getting and will get on this, I think we can harmonize these rules and avoid the concern that you are raising. I am

confident about that.

Mr. {Shimkus.} Okay. You understand the concerns, and our basic premise is, if it is the entry point safe for humans, understanding you have got to figure out the endpoint and the processes, but it should be safe for animal feed for the most part.

Mr. {Taylor.} Yes. And the system is all about being risk-based and it is about not duplicating effort, and so there are any number of ways in which we are being very careful to be sure that we are getting the control we need but not having duplicative controls.

Mr. {Shimkus.} But you don't know of any record in that process of animal feed through that processes has caused any human health indications? There has been no report to anybody that there has been any incident?

Mr. {Taylor.} I am not aware of it sitting here. If others are, we will put that in the record.

Mr. {Shimkus.} And I don't think there is either, and that is the point of the debate.

Mr. {Taylor.} Thank you.

Mr. {Shimkus.} So I appreciate it.

Let me also then go to, you know, there is a great deal of variability in food products and processes, as you know. Therefore, a successful testing program is tailored to a specific circumstance related to each product in manufacturing operation. How will the regulation be written to assure that testing is risk-based and not prescriptive, very similar to the other previous question but this is really just in the initial phase.

Mr. {Taylor.} That is very important. I think we all know from long experience that certain kinds of testing programs and certain kinds of facilities can be important to verifying the controls are working. Peanut butter processing facilities, for example, where salmonella in the environment can contaminate peanut butter and cause a significant problem. Most companies undertake so-called environmental monitoring testing of the environment to verify that the sanitation and other measures are preventing the presence of that pathogen.

But it is also well understood that those testing programs have to be based upon the particular risk considerations, the processing systems and the products in

that particular facility. There is no one-size-fits-all solution, and I think if we are agreeing on anything across the board, one-size-fits-all doesn't work on any dimension really here.

Mr. {Shimkus.} Well, and I think that is what we find out in our committee, and going back to the hearing yesterday on another subject, risk-based is where we need to be, and really, the private sector, if you evaluate their testing processes and you find that it adequately does the test, the concern is, government will be prescriptive and they will say test it this way where we know that the industry has already got a pretty good process of ensuring safety and efficacy.

Mr. {Taylor.} If I may, just really briefly, I mean we know there are firms that have invented the standard of care, if you will, or have programs that are in place and are doing the right thing and in fact go beyond what we would end up mandating. We have to have rules that are flexible enough to not disrupt those ongoing processes while also setting a standard of care that is clear and implantable by those who aren't there yet and who FSMA is intended to bring up to an appropriate standard. So that is the balance we need to

strike in the final rules.

Mr. {Shimkus.} Thank you very much.

Thank you, Mr. Chairman.

Mr. {Pitts.} The Chair thanks the gentleman and now recognizes Mr. Matheson 5 minutes for questions.

Mr. {Matheson.} Well, thank you, Mr. Chairman. I appreciate the committee holding this hearing. I think this is a good thing for Congress after it passes a law to take a look at how it is being implemented. I think that is something we ought to do a lot of in Congress across all committees, so I do appreciate this hearing.

Mr. Taylor, I have heard some concerns raised, and this may have been covered a little bit before but I am going to ask you again anyway. I have heard concerns raised about the language in the proposed rule on the preventive controls. Some have raised a concern that the use of the phrase ``reasonably likely to occur'' in the rule is different than the Congressional intent, which would be ``reasonably foreseeable'' that is in the law, that is the term. Can you talk about these concerns, the validity of these concerns, what these different--you know, to me, these are two

different sets of language, and I don't know want to get into semantics, but sometimes it matters, so can you talk about that, about what that means?

Mr. {Taylor.} Sure, and we don't need to go into a lot of detail to sort of get what is the central important point. It is one that we were just discussing. Concern really rises from folks whose systems are advanced, they are established, they are clearly achieving the sort of prevention that FSMA is about, and we want to be sure that we don't use language and rules that would create a concern about forcing change in those practices that don't make a practical difference for food safety, and we have had a lot of dialog with industry stakeholders, particularly on this point, and we think there is a way to solve this and manage this so that we achieve the purpose that I just recited. We need flexibility for them but a standard that we can implement and enforce where needed for those who aren't there yet.

Mr. {Matheson.} So to the extent you have heard concerns raised about this, you are trying to work with stakeholders right now to figure out a way to--

Mr. {Taylor.} Absolutely. We have very active dialog.

This is a solvable issue.

Mr. {Matheson.} That is great.

The next question I would ask is, you know, the law asks for an increase in the number of domestic food facility inspections. Do you have any indication of how many inspectors that is going to take and what the costs are going to be for this?

Mr. {Taylor.} Well, I think one of the things that is fortunate is that with the increases that have happened over the last few years, we feel that we have the number of people we need to meet that domestic inspection frequency mandate, so that is a part of FSMA where we think we can hit the number. What we don't have is the resources right now to retrain and reequip those inspectors to work in this sort of modern preventive controls environment where we want to be focusing on the public health outcome and not just a checklist of regulatory requirements. So we need that, and then--

Mr. {Matheson.} Do you have those resources, by the way?

Mr. {Taylor.} We don't have that, and that is the kind

of additional funding that we need in order to implement FSMA successfully to really get the full modernization benefit that FSMA is about.

Mr. {Matheson.} Do you have about what that gap might be?

Mr. {Taylor.} I will stick with the request in the President's budget and it included about $225 million in fees, which would go a long way towards closing the FSMA funding gap. The total FSMA funding gap that Secretary Sebelius recited to Congress in the spring of last year was $400 to $450 million above our 2012 base. We took a step back in 2013. We took a step forward in 2014. We still have a sizable gap.

Mr. {Matheson.} Do you plan to use third parties to conduct some of your inspections?

Mr. {Taylor.} No, sir. We will partner with state governments and other governmental partners on inspection. We do see the value of working to strengthen the private audit system that the industry has developed over the last number of years, and the law itself, as you know, mandates that we establish an accredited third-party certification

program for certain import oversight purposes that are fairly narrow and targeted, but we would not ever think of private audits as a substitute for our inspection.

Mr. {Matheson.} For the ones that are not domestic, for the ones overseas, how is that third-party system implemented so far? How is that going?

Mr. {Taylor.} The way in which Congress has prescribed that accredited third-party auditors be involved in certifying the safety of imports is in two situations. One is, as part of the so-called voluntary qualified importer program, which is the expedited entry system for people who are going the extra mile, that would include an accredited third-party audit of the foreign facility. We also have the authority to mandate an accredited third-party audit for particular high-risk situations, but those are the specific uses for which the accredited third-party audit is in the law.

Mr. {Matheson.} All right. Well, thank you for your answers, and Mr. Chairman, I will yield back.

Mr. {Pitts.} The Chair thanks the gentleman and now recognizes the chair emeritus of the full committee, Mr.

Barton, 5 minutes for questions.

Mr. {Barton.} Mr. Chairman, thank you. I am going to yield my time to Mr. Walden of Oregon.

Mr. {Walden.} I thank the chairman emeritus, and I thank the chairman for holding this hearing, and Mr. Taylor, it is good to see you again. I have appreciated the meetings that we have had with you and your team and your openness to taking a look at how some of the ag practices actually occur on the ground and may be in disconnect with the original rules, and I appreciate your coming out to the Northwest and bringing your folks to meet with a lot of our growers out there, especially on the east side of my district with the onion growers who actually are having their annual conference about now and to witness firsthand how irrigation works and the kill step in growing onions and safety of how they do it, so I was really pleased you were open, you listened, you pulled back the regs that would have been in conflict and moved forward, so I commend you for that, and I hope the science that our OSU lab produced out there on this issue involving onions was helpful. I sense that it was in your decision-making.

My question relates to, as you go about redrafting the rules and what interactions you might be having with farmers and ranchers out in the West, certainly in districts like mine, and as you write these new rules, obviously that continued communication is important to the extent it is allowed under your rulemaking process.

Mr. {Taylor.} Thank you, Mr. Walden. The trip to your district was just a great learning experience for all of us, and we appreciate the hospitality that you and your colleagues there showed us.

But yes, when we reopened the comment period and proposed alternative language on certain key provisions, there will be at that point an opportunity to have not only written comments but to engage directly with people who will have perspectives on what we have re-proposed, and we will be re-proposing on the water standard including the standard itself and the testing regime that we propose, so there will be interest, no doubt, in your community. We look forward to whatever dialog would be useful. And the research that is going on in Oregon at the University is helpful work, and we are collaborating closely there, and I think we can address

the concerns that we heard about out there.

Mr. {Walden.} And as you know, there was some language in the Farm Bill that dealt with some of these issues around the rules in terms of the economics and I think in terms of the science as well. Obviously it is critical that we get a science-based set of rules that actually work in the real world. I know when I was out and met with our onion growers, toured around, as you and your team did at another time. They were just pointing out how from field to field you could have radically different readings for no real reason that is even manageable, and meanwhile I think one of the growers told me they have been growing onions there for a hundred years and never had an outbreak of salmonella, and they bagged I don't know how many millions of bag every year. I thought that was a pretty big sample size if you were going to do a statistical analysis of risk, and so I appreciate your pulling back on those rules. It is just essential whether it is there or our cherry and pear and apple growers or blueberry growers that we get this right and not upend them. And of course, they have concerns about imported foods, do they meet the same ag practices we are putting on

American farmers and we ought to be careful. None of us wants spoiled food. None of us wants the illnesses. I actually helped lead some of the investigations into Peanut Corporation of America but that was a case where they did things that were against the law to begin with, and they are paying a very severe penalty, as they should, for their actions. So we want to make sure we have got this balance right between safety of our food supply that allows for productive agriculture to continue in a way that works.

Again, I thank you for listening to us and actually coming out on the ground, and I hope that as we go forward with those rules that there will plenty of time for our folks that are going to have to abide by them to have full input.

Mr. {Taylor.} Absolutely. We are working toward the same goal, and we will get there by working together, so we look forward to that.

Mr. {Walden.} Thank you. Mr. Chairman, I yield back.

Mr. {Pitts.} The Chair thanks the gentleman and now recognizes the chairman emeritus of the full committee, Mr. Dingell, 5 minutes for questions.

Mr. {Dingell.} --it is important to ensure the safety

of imported foods. It also needed money and personnel to do its job. FSMA was a significant step forward, but we have a lot of work left to do. The CDC estimates 48 million people get sick from foodborne illness each year. Furthermore, 128,000 people are hospitalized and 3,000, at least, die. Although we are not going to get these numbers down to zero, we must continue to focus on improving food safety in this country, particularly that which comes in from abroad. While FSMA represents a significant increase in authority for the FDA, Congress has only solved half the problem.

We also need to give FDA the resources it needs to fully implement FSMA and to create a proper, adequate 21st century food safety program.

Mr. Taylor, I request that you answer these questions yes or no. Does FDA have the resources in money and personnel it needs to properly implement the Food Safety Modernization Act? Yes or no.

Mr. {Taylor.} No, sir.

Mr. {Dingell.} I would appreciate it if you would submit to us a proper survey of what you need in the way of money to accomplish this purpose.

The Obama Administration's fiscal year 2014 budget request included $59 million in food facility registration fees and inspection fees, and $166 million in food import fees to help fund food safety activity. Does FDA continue to support user fees to pay for FSMA? Yes or no.

Mr. {Taylor.} Yes, Mr. Dingell.

Mr. {Dingell.} Congress gave FDA a big job to do but clearly not enough money to do it right. I would note that the House-passed version of FSMA contained user fees that would have helped solve the problem, but this provision did not make it into the final version of the legislation. Many stakeholders continue to have concerns both about the timing and the substance of FSMA regulations. I would posit that these issues may not have been a problem if we had done the right thing early on and given the FDA the resources that they needed.

Today, we find FDA under court-ordered deadline to finish all FSMA regulations by June 2015. Do you have the money to do that?

Mr. {Taylor.} Yes.

Mr. {Dingell.} You do?

Mr. {Taylor.} To get the regulations issued, yes, sir.

Mr. {Dingell.} All right. Passage of FSMA was the product of collaboration between industry, consumer groups and the agency, and I think the industry deserves accommodations for the fine work they did on that matter from start to finish. I hope that this process will continue as FDA moves forward with the finalizing of these critical regulations.

Next question. Mr. Taylor, will FDA commit to working with all stakeholders in considering public comments as the agency works to meet the June 2015 deadline for issuing final regulations? Yes or no.

Mr. {Taylor.} Yes, absolutely.

Mr. {Dingell.} Now, one critical part of FSMA is increased inspections of both foreign and domestic food facilities, and FDA will need to hire more inspectors to properly do the job, and I happen to think that we desperately need more inspection of foreign producers and more scrutiny and surveillance of foreign producers and others who enter the food supply chain. Is that a correct assumption?

Mr. {Taylor.} Yes, that oversight is important.

Mr. {Dingell.} Now, FDA will need to hire more inspectors to properly do the job. Is that right?

Mr. {Taylor.} Yes.

Mr. {Dingell.} And you are going to have to have some more for overseas?

Mr. {Taylor.} Yes. We have the resources for domestic but not for overseas inspection.

Mr. {Dingell.} Does FDA have the resources to meet the hiring targets set by FSMA? Yes or no.

Mr. {Taylor.} Yes, for--

Mr. {Dingell.} You do?

Mr. {Taylor.} No, no, no.

Mr. {Dingell.} You do not have those resources?

Mr. {Taylor.} Those targets in the law, we do not have the resources to meet them.

Mr. {Dingell.} I don't want the record obfuscated on this matter. Will you submit, please, a detailed response for the record including the resources you need and how many FTEs, or full-time equivalent employees FDA needs to hire?

Mr. {Taylor.} Yes, we will.

Mr. {Dingell.} And how many do you plan to hire?

Mr. {Taylor.} Well, our plan will be the function of the resources we get, and we will lay that out in the response.

Mr. {Dingell.} Submit for the record, if you please.

Mr. {Taylor.} Yes, sir.

Mr. {Dingell.} FSMA also contains some exciting new authorities that are already in place and are protecting the American people including mandatory recall of tainted food products. That is a new authority to the agency. Is it working?

Mr. {Taylor.} Yes.

Mr. {Dingell.} Does it need change?

Mr. {Taylor.} It works. We don't think it needs changed.

Mr. {Dingell.} Has FDA exercised a mandatory recall authority under FSMA? Yes or no.

Mr. {Taylor.} Yes. We have initiated the process twice. The firms have wisely voluntarily recalled once we invoked the mandatory authority.

Mr. {Dingell.} They didn't fight you on the recall?

Mr. {Taylor.} No, sir. That is the power of this authority.

Mr. {Dingell.} Are you comfortable that the authority is sufficiently sweeping and adequate to carry out your responsibilities there?

Mr. {Taylor.} Yes, within the food part of FDA.

Mr. {Dingell.} Food?

Mr. {Taylor.} Yes.

Mr. {Dingell.} Now, you do not have the authority with regard to pharmaceuticals, do you?

Mr. {Taylor.} That is correct.

Mr. {Dingell.} And how about other things like devices, knees, hips?

Mr. {Taylor.} You are leading me out of my territory, Mr. Dingell, but there are gaps in FDA's authority on the medical products side with respect to mandatory recall.

Mr. {Dingell.} I want to thank you for this. I believe that mandatory recall is a useful tool in any emergency and should be expanded to the other areas that we have just been talking about in the agency's jurisdiction.

Now, FDA has a large task ahead of it, and as the agency

works toward final implementation of FSMA, I urge the agency to move quickly during the rulemaking process while continuing to engage in a collaborative process with the stakeholders because working with the stakeholders will be the way that you will get their support, their wisdom, and the ability to do your job better.

Mr. {Taylor.} Thank you, sir.

Mr. {Dingell.} Mr. Chairman, you have been most courteous in giving me extra time, for which I thank you.

Mr. {Pitts.} The Chair thanks the gentleman and now recognizes the vice chair of the subcommittee, Dr. Burgess, 5 minutes for questions.

Dr. {Burgess.} Thank you, Mr. Chairman. As I was listening to that exchange with Chairman Dingell, it took me back to the heady days when he took the gavel from Mr. Barton, and in fact, if you look back at that time, the budget for the Food and Drug Administration was about $1 billion and today it is more than that. Is that a fair statement?

Mr. {Taylor.} Yes.

Dr. {Burgess.} It is about two and a half times that

amount?

Mr. {Taylor.} In budget authority, yes.

Dr. {Burgess.} So--

Mr. {Taylor.} That is for the agency as a whole, not for the food side of things.

Dr. {Burgess.} Correct. But even with the sequester, the Food and Drug Administration received from Congress an increase of nearly $100 million over the amount provided in fiscal year 2013, and in fact, you got several million dollars over the agency's budget request. Is that not a true statement?

Mr. {Taylor.} We got what we asked for on food safety to implement FSMA, yes.

Dr. {Burgess.} Okay. So nearly a billion dollars, $900 million, was targeted to the food and safety network. Is that correct?

Mr. {Taylor.} Yes, sir.

Dr. {Burgess.} So Mr. Dingell was talking to you about the--he wanted some detail on the resources that you think you might need. I guess that means resources in addition to that $900 million was what he was asking for, but can you

provide us the accounting of how the $900 million has been spent so far that was targeted to the Center for Food Safety and Applied Nutrition?

Mr. {Taylor.} We can do that. Just to be clear, that $900 you are referring to is total funding for all food-related activities at FDA. We have certainly deployed a huge part of that to FSMA implementation but those resources also cover what we do in food additive regulation, in nutrition, dietary supplements, you know, a range of other programs that we are responsible for. That is not all for implemented the Food Safety Modernization Act, but we can certainly provide you that information.

Dr. {Burgess.} Could you provide us that with a level of detail so we would be able to--the key here is discernment. Chairman Dingell asked you for what you might need in the future but I would like to know what is being given and what is being spent and how it is being spent currently.

Mr. {Taylor.} Yes, indeed.

Dr. {Burgess.} Let me ask you, because he brought up the issue of foreign suppliers, the scrutiny of foreign

producers, I think, was the terminology he used. How are you organized or structured to make certain that there is that fairness that he was talking about, that we are not discriminating against local producers that are advancing foreign producers at the expense of local producers?

Mr. {Taylor.} Sure. So the answer to that is being able to implement the full FSMA import toolkit that we have been given to create this new import oversight system. The foundation for it is the foreign supplier verification program requirement, which makes the importer accountable for having a plan through which they can document that they know where their product is coming from, their imported product, and they can verify in an appropriate way based upon risk that the proper controls have been implemented at the foreign supplier point. That private sector responsibility for supply chain management is the foundation for this new import system and it is much more preventive and, again, reliant on industry. It will work, though, to the extent that first we can have people who are trained and we have adequate numbers of people to check that those systems really mean something, that they are not just words on a page, so verifying that

those audit systems are working--

Dr. {Burgess.} And I think that is the key because we certainly heard through hearing after hearing after hearing in 2007 and 2008 and on into 2009 about where the problems existed, and there were imports that were coming in that had no business coming in. Are we better prepared today to deal with those problems?

Mr. {Taylor.} Well, are building a system that will enable us to be prepared.

Dr. {Burgess.} But we are not there yet.

Mr. {Taylor.} No, we are not there yet. I mean, again, I think there is--you know, FSMA has stimulated a heightened recognition and reflects a heightened recognition as well across the food system that we need to be improving how we manage supply chains globally as well as domestically, but FSMA won't fulfill its purpose until we not only have the regulations promulgated but until we can actually verify that that system is working. And again, Congress--

Dr. {Burgess.} My time is running out. What are the barriers to promulgating those regulations right now?

Mr. {Taylor.} It is just a lot of work, a lot of

issues, but we are deploying the people to do that. You know, that is our priority is to get those rules done.

Dr. {Burgess.} But when this legislation was passed by Congress in 2010, the promise was that we were going to prevent these problems that had been happening with such alarming regularity that we were going to protect the American people, that the FDA had not been able to keep up with the effects of globalization but that was going to change. When can we tell people to expect that change we can believe in to have happened?

Mr. {Taylor.} FSMA will fulfill its purpose when we are able to implement it, and it is not just the rules. It is the ability to oversee the rules. So it is a process that over the next several years will have the benefit that you seek but it is not an overnight process to build a modern food safety system for this century.

Dr. {Burgess.} Several years, meaning it could be a decade?

Mr. {Taylor.} I think it won't be that long before you will have rules in place and the ability for us to verify that those rules are being implemented if we get the

resources.

Dr. {Burgess.} I hope not, because a decade actually would be 2020. That would be the 10 years from the passage of the Food Safety Modernization Act.

Mr. {Taylor.} I understand. Yes, sir.

Dr. {Burgess.} Thank you, Mr. Chairman. I will yield back.

Mr. {Pitts.} The Chair thanks the gentleman and now recognizes the gentlelady from California, Ms. Capps, 5 minutes for questions.

Mrs. {Capps.} Thank you, Mr. Chairman.

Commissioner Taylor, I thank you for your testimony, and I am glad to be here today ensuring that the Food Safety Modernization Act is and continues to be as effective as possible. I understand that the FDA faces an immense scope of responsibility in implementing the Food Safety Modernization Act. You mentioned that FSMA will only be as effective as its on-the-ground implementation, and I agree.

Agriculture is one of the primary economic drivers in my district, and so these issues certainly hit close to home. Food safety for fresh produce such as leafy greens is

obviously incredibly important. As you may know, following an earlier food safety crisis in 2007, California leafy green growers, many of them that are in my Congressional district, took it upon themselves to raise the industry safety bar by creating the California Leafy Green Products Handler Market Agreement, a mouthful, LGMA for short. Since its founding, LGMA has become a strong collaboration between government and farming communities. They incorporate science-based food safety practices and mandatory government inspections in an effort to ensure safe leafy green products. The LGMA has already been, for all intents and purposes, verifying the leafy green industry's compliance with food safety practices that meet or exceed the specific rules being proposed under FSMA. Obviously we all want to make the processes as efficient and effective as possible, ensuring high standards without creating unnecessary redundancies. I just met with the California Farm Bureau folks, a couple from my district, just now. This is very much on their minds.

So my question to you, can you tell me what the agency is doing to collaborate with groups like LGMA in this process? How will FDA work with industry to verify

compliance with the new FSMA laws?

Mr. {Taylor.} Thanks very much for the question. The Leafy Green Marketing Agreement is a real demonstration of leadership on that part of that industry, which has come about in response to some of the outbreaks that were very costly and disruptive for that industry, and the standards that they have put in place and that they monitor themselves are very positive and are standards that, as you say, will likely meet or exceed what the federal standards will be, and we certainly, as we think about how we verify compliance with this broad range of standards, absolutely want to cooperate with and place reliance where appropriate on these private efforts to monitor and verify and demonstrate that their product is being produced in accordance with these standards.

So we meet with, we collaborate with the folks involved in the Leafy Green Marketing Agreement. It is a very positive part of progress on food safety, so we embrace it.

Mrs. {Capps.} So it is not like one person has the rules and the other person is trying to comply, but you are all in it together?

Mr. {Taylor.} Enormous dialog and recognizing that we

want to capitalize on what leaders in the industry have learned and then, again, not disrupt those practices that are working just out of some--

Mrs. {Capps.} Let me just push this a little further, not that I don't agree with what you are saying, but as you know, unfortunately, contamination in our food supply repeatedly has threatened the health of Americans over the years, and you mentioned how costly it is to the industry as well. These events have really initiated such fear in consumers, considering the safety of our food supply, the very food that is the best for us. So we need more of a win-win, and I think that is behind this effort here, a bipartisan effort, to enact the Food Safety Modernization Act.

Now, several years post enactment, how have we become more prepared? Do you think we are in a position where we could not just prevent but anticipate the next big outbreak? How will the FDA be more effective in dealing with the next big food contamination emergency?

Mr. {Taylor.} I think there are a couple of things. I mentioned already that I think FSMA is part of a process

where we have been making progress in the private sector and through collaboration between government and private sector to put in place practices even as we anticipate FSMA being implemented, and that is one way in which I think we are hopefully making progress. We have also done a lot of work at FDA and with the CDC to be better at detecting outbreaks earlier. We have created a focus, specialized team at FDA to do early detection of potential outbreaks, to respond more quickly, and then importantly, to learn from outbreaks. And so we have investigated, for example, the cantaloupe outbreak that killed 33 people associated with Listeria in cantaloupe. We did an investigation of what the potential cause was, and then we have been out collecting additional data to inform the cantaloupe industry about measures that can and should be taken.

So there is a lot of work going on which will continue, even as we get the regulations in place and are able to verify that the practices that we are learning work are in fact being implemented comprehensively, not just by the leaders but comprehensively across the system.

Mrs. {Capps.} Okay. Great. I will yield back.

Mrs. {Blackburn.} [Presiding] The gentlelady yields back. Dr. Murphy for 5 minutes.

Mr. {Murphy.} Thank you, and welcome here. We appreciate your testimony. It is very enlightening.

I am wondering, the CDC a couple years ago said that there was a reduced or different risk in foreign imported products versus United States. Does that difference still exist?

Mr. {Taylor.} You know, the data that could be quantitative about this are limited but CDC did report increases in significant numbers of outbreaks associated with imports. And so we know that food can be jeopardized, whether domestic or imported, but imports are very much a public health concern.

Mr. {Murphy.} I am just curious then. Is there a difference in seafood, meats, fruits, vegetables? Any categories in terms of which are at higher risk, or does it vary?

Mr. {Taylor.} It varies across category, and again, CDC has put out the best data on that, and again, I don't have time to go into detail but we could provide that for the

record.

Mr. {Murphy.} I appreciate that. Also, there have been concerns that have been raised in some sectors in the public about genetically modified organisms, genetically modified foods. While some may have concerns of risk, are there potentials that you are going to explore in the future with regard to some modifications that would lead to reduced risk for foodborne illnesses among some of these?

Mr. {Taylor.} Regrettably, I am recused from working on matters related to genetically modified organisms, and so if you don't mind, we will--

Mr. {Murphy.} That is fine. You had mentioned that you are taking steps to inform some growers, some products of actions that they can take to improve safety. I appreciate that. Are you also providing technical assistance or support to them in particular to help them comply with rules?

Mr. {Taylor.} That is a very important part of our strategy and our plan. Even well before the rules were final, we have created in collaboration with USDA and with the State Department, the Department of Agriculture, the Produce Safety Alliance at Cornell University, which is all

about developing training and technical assistance materials for small growers. So this is central to our strategy. Educate before you regulate is a mantra that many of us are using.

Mr. {Murphy.} So you would have been working directly with some of the growers and food manufacturers, listening and communicating with them on those?

Mr. {Taylor.} Yes, through their organizations and directly working with them.

Mr. {Murphy.} Thank you. When a product is linked to some sort of outbreak and consumer confidence plummets, in many cases the company that had nothing to do with the issue will see sales of similar products decline, even though they are not part of that. How does the Food Safety Modernization Act address this to prevent some single outbreak from crippling a whole sector of the agricultural industry?

Mr. {Taylor.} That is a very important point because that is why many people in the industry are supporting this so strongly because they can be affected by what others do. The fundamental thing, of course, is to prevent these outbreaks as much as we possibly can so you don't have the

loss of consumer confidence and market disruption, and FSMA will contribute to that greatly.

The other piece, I think, is this effort to detect outbreaks more quickly. The sooner we can detect an outbreak and contain it, the less disruption there is, and so both of these things, prevention and response, work together.

Mr. {Murphy.} Now, also in addition to what is being done with growers, food processors, manufacturers, distribution, grocery stores, et cetera, what is being done in terms of public information campaigns to help all of us and our households know what should be done at home in terms of food storage, food preparation, what should be looked for in products that could tip off ways that the food may be containing some sort of illness?

Mr. {Taylor.} That is a really important question, and both FDA and USDA have consumer education programs. They are fairly modest in scale. We work with the Partnership for Food Safety Education, which is a collaborative undertaking between industry, consumers and government. We need to do more on consumer education as part of the public health prevention system in our mind, and one thing that has

happened over the last year or two has been an Ad Council campaign, for example, that has tried to reach consumers through the advertising media. But there is more to be done to really understand how consumer education can be done in a way that does change behavior and reduce risk. We can't depend on consumers to solve the public health problem but they are part of the ability to minimize risk, and we want to work in that as well.

Mr. {Murphy.} I hope so. I mean, I can't recall ever seeing an ad of any kind that talks about some of these issues with food safety.

Mr. {Taylor.} It is very limited.

Mr. {Murphy.} And yet we are the last part there. Other than knowing, you know, if there is a bulging can, don't open it or eat it, or look at the date on something or what most people do is simply smell the milk, and if it smells bad, don't have it, but other than that--I hope that that is an area because that is an area of public outreach I think is essential for people to know that.

Mr. {Taylor.} Agreed.

Mr. {Murphy.} All right. Thank you. I yield back.

Mr. {Taylor.} Thank you.

Mrs. {Blackburn.} The gentleman yields back. Mr. Green, 5 minutes.

Mr. {Green.} Thank you, Madam Chairman, and I thank the chair and the ranking member of the committee for this hearing today. Commissioner Taylor, I want to thank you for being here and for your patience with us.

I have a district in Houston, in fact, the Port of Houston, and so a few years ago I had the opportunity to be on the docks with not only FDA inspectors but other inspectors for our food safety, and in Texas, we have not only a number of ports that bring in but we also have a huge land border that brings in untold amount of foodstuff from Mexico. Ensuring that the roles are effective in protecting public health and supporting industry best practices is critical. I believe that two of the most contentious rules you are developing are those establishing prevention, preventive controls and produce safety standards. It seems to have taken a long time for FDA to release them, and in fact, it may only have been because of the court order that you were able to release them when you did, and since that

release you have delayed the close of your comment periods and announced you may be re-proposing parts of each of them.

My question is, considering the foundation of these rules are for establishing a preventive food safety program, can you tell us why they have taken so long to develop their release? I would hope that the proposed rules in working with the stakeholders you realize you have gone back to the drawing board, if that is part of it. But like my colleague from Texas, Dr. Burgess, said, it has been 3 years since the law passed. Can you describe the process you have gone through to develop them including engagement of those stakeholders and explain what makes them so contentious and can you explain their importance to public health?

Mr. {Taylor.} Sure, sure, and I appreciate your impatience. I have experienced it myself, and we are all working hard to get this done as quickly as we can. We do think it is critical to get it done right. We are really laying the foundation for the next 50 years of successful food safety oversight in this country, and I think we do have enormous momentum with the seven proposals we have published since last January.

I think one reason it takes time is because these proposals do have to work together, first of all. It is like putting a puzzle together and there are a lot of complexities among the provisions, but also we can't lose sight of the fact, and this gets to the question of why there are--you know, we have had a very vigorous dialog with people with different points of view. We are building a new system that affects a lot of economic activity and a lot of actors in our food system, and so understandably, people have perspectives, they have information that they want us to consider, and we feel obligated to and we want to because it is how we will get a good set of rules that will work for the long term. So we feel good about the dialog we have had. We think the process has real momentum. We are working to meet the court deadlines and balance these two considerations of speed and ability to be sure everyone is heard and we have got the best possible rules at the end of the day.

Mr. {Green.} My other concern is improving foodborne illness surveillance. It is a critical part of the Food Safety Modernization Act. I have been told that foodborne illnesses are woefully underreported and that the quality of

reporting varies dramatically by State. I would like to know what the FDA is doing and planning to do to improve reporting of the foodborne illnesses, and as part of your answer, could you speak to what the FDA and CDC are doing to improve capacity at the State and local level to detect and track outbreaks?

Mr. {Taylor.} The surveillance of foodborne illness, of course, is CDC's responsibility, and they are charged in FSMA with improving foodborne illness surveillance. As I indicated, we work very closely with CDC on the early detection of outbreaks but the ability to respond to outbreaks is very much a function of what State health department capacity is because most of the legwork in a foodborne illness outbreak is done by State and local health departments, and they have suffered their own budget cuts. So there is a real resource sort of infrastructure problem in our ability to detect and oversee and then estimate the frequency of foodborne illness, and again, CDC manages that part of the food safety system but we are dependent on it and place the importance on it as much as anybody.

Mr. {Green.} Like my colleague, our chairman emeritus,

I am concerned about not having the resources to do your job, and is this delay for the last 3 years now, is that because of some of the lack of resources that Congress may not have applied?

Mr. {Taylor.} No, sir. I think the time it has taken is a function of the complexity of the process, and we have deployed our people and put great--

Mr. {Dingell.} Will the gentleman yield?

Mr. {Green.} I would be glad to yield.

Mr. {Dingell.} --

Mr. {Green.} And I appreciate the Chair's patience. Sometimes some of us support a unicameral Congress instead of having two bodies.

Mrs. {Blackburn.} The gentleman yields back.

Mr. {Taylor.} Can I just clarify the point that I wanted to make about this? By redeploying people within FDA and the resources we have gotten from Congress, we can issue the regulations. You know, we can put the rules on the books. Where we are lacking resources and where the fees would be essential, the additional resources, is in implementing the rules, and that is where we get the food

safety and economic benefit if we implement the rules they are envisioned and intended to have this modern preventive system. And that is where we have the big funding gap for FSMA is the implementation of the rules once they are promulgated.

Mrs. {Blackburn.} Okay. The time for the gentleman from Texas expired. I recognize myself for 5 minutes.

Mr. Taylor, we are all concerned about the implementation and what that structure would look like, and of course, a risk-based structure makes sense but I think that what we know is that 1 percent of the domestically produced commodities account for 95 percent of the illnesses, and those commodities should clearly be the focus of any risk-based system, and I think that part of our concern is why you have chosen to broadly regulate commodities that have not been associated with human foodborne illnesses.

Mr. {Taylor.} So let me give you a little bit of--this is in the produce context, I think, and--

Mrs. {Blackburn.} Yes, it is.

Mr. {Taylor.} And do I have to respectfully say I am not sure the basis for the 1 percent, 95 percent point but I

would be happy to have dialog about that.

There is no question that there is some commodities that have been more associated with significant outbreaks that we have been able to detect and that CDC has reported than other commodities. There is no question about that. One important point is that our ability, as we have been discussing, to detect illnesses and outbreaks is limited by lack of resources, so there is greater underreporting of illnesses that occur.

What food safety experts recognize and what Congress recognized in passing the law is that when it comes to produce, that if you don't pay attention to the quality of the water, the safety of the water you put on the produce that people are going to eat or you don't pay attention to the basic hygiene of the workers handling the food, you know, if you don't pay attention to what is happening when fertilizers are added that can potentially be carriers of pathogens, you know, Congress identified these basic vectors of possible contamination and directed us to establish standards that are reasonably necessary to prevent the introduction of reasonably foreseeable hazards. So it is a

prevention syndrome. It is not a response--

Mrs. {Blackburn.} Right, and I--

Mr. {Taylor.} --to outbreaks, you know, regime in FSMA. And so that--

Mrs. {Blackburn.} I appreciate that, but talking to my Tennessee farmers about the produce safety rule, they are very concerned with the lack of flexibility. Now, I was pleased to hear you tell Mr. Walden that you are going to do a revisit on the water rules because you do have to take into account the regional and the local water supply issues that are there, but I think it is important, and I wish that you all would consider the relative risk and the comparative benefits associated with regulating some of these individual commodities. I will tell you, some of the rules are a head scratcher, and I will give you an example. Kale listed as a commodity and noted never consumed raw.

Mr. {Taylor.} We learned through the comment process, and so that--

Mrs. {Blackburn.} Well, I was going to offer to make a kale salad for you, so I think it is interesting, those are the things that you read and it causes you to wonder if those

that are writing these rules have ever set foot on a farm or if they have ever been to a Farm Bureau dinner where everyone is bringing their favorite dish and enjoyed some of these wonderful items. So I hope that listening to the questions that we are asking that it points up some of the things that we need to be bringing to your attention.

Mr. {Taylor.} Sure.

Mrs. {Blackburn.} And through the comment period, we know that you are going to come up with some of these.

I think that another thing, before my time expires, that I want to highlight with you is the factors or standards that the FDA used to establish its list of covered or exempt produce. This is something that has been questioned is, how you all came about those and what list would be regularly reviewed. So just know that all of that is on our list and we are going to continue to conduct oversight very carefully, and with that, I will yield back the balance of my time, and Mr. Griffith, you are recognized for 5 minutes.

Mr. {Griffith.} Thank you, Madam Chair.

Thank you for being here this morning. In the FSMA law, Congress specified that facilities should identify reasonably

foreseeable hazards, but my understanding is, in the proposed rules, the FDA is using ``reasonably likely to occur'' in the proposed preventive controls use. This language is different from law and forces the food industry to shift from focusing on what will occur to what can occur. Does in fact FSMA use ``reasonably likely to occur'' as a basis to define the threshold for determining preventive controls?

Mr. {Taylor.} That is not the term used in the statute. It comes from our experience with HACCP preventive controls, but again, we have heard a lot about this issue and I think we have a way to address this.

Mr. {Griffith.} Okay. And I just have to point out that, you know, I would have got in trouble. I am not a food expert. I was a lawyer by training. But my law school professors hammered into us the big difference between the possibilities that an expert witness might testify to or may testify to, and the probability, which is a different thing, and I think that is what people are concerned about. Any of us could be hit by a meteor, they are out there, but that doesn't mean we need to be taking evasive action when I cross the street from this building to the next.

Mr. {Taylor.} Yes, sir.

Mr. {Griffith.} Likewise, if there is a probability, I do need to be watching out for those cars that are coming down the road.

Mr. {Taylor.} Understood.

Mr. {Griffith.} And so I do appreciate that.

Also I am concerned, I just want to make sure that I have got this clear that, you know, I represent a rural area of the country, and I want to make sure that all my small farmers aren't getting into any kind of headaches and hassles that would close them down. It is my understanding that if you are a farmer who is growing fruits and vegetables and you are selling directly to the end-use consumer, that unless you have sales of $500,000 a year on average over 3 years, that you are not covered by these rules. Is that correct?

Mr. {Taylor.} That's correct.

Mr. {Griffith.} All right, and I do appreciate that.

Likewise, for people that are canning vegetables, making jams of manufacturing honey for farmers markets and local consumption, am I correct also that they would be exempt from the preventive control rules?

Mr. {Taylor.} If they have sales below that $500,000 threshold, yes, sir.

Mr. {Griffith.} All right. Are there new requirements that these smaller farmers or the farmers who are selling right at their farm or at the roadside stand or at the farmers market that they would have to meet in order to be in compliance with FDA's implementation of FSMA?

Mr. {Taylor.} For produce growers who are exempt under this provision, the only thing they are required to do--this is by statute, by the law itself--is post information about their location so that their direct-to-consumer customer can come back to them if they have a problem.

Mr. {Griffith.} Okay. And I appreciate that. I also will tell you that I appreciated it very much in previous testimony when you said that you all recognized that you can't have a one-size-fits-all approach. That is very refreshing. A lot of people are concerned both about that and about folks getting carried away and suddenly we are shutting down the small farm operations, and your testimony has made me feel better about that, and I appreciate you being here, and with that, Madam Chair, unless somebody wants

my time, I will yield back.

Mr. {Pitts.} The Chair thanks the gentleman and now recognizes the gentleman from Florida, Mr. Bilirakis, 5 minutes for questions.

Mr. {Bilirakis.} Thank you very much. I appreciate it. I was over at the other hearing.

Mr. Taylor, I just wanted to follow up on an earlier question, I believe Chairman Shimkus asked this, about food byproducts being used for animal food. In Florida, the citrus industry sells orange peels, as you know, and oranges have fallen off the tree for animal feed. I think there are large environmental and sustainability issues that FDA may be overlooking.

If the proposed rule drives up the cost of byproducts converted to animal feed chain, many small and midsized manufacturers will abandon the production of feed ingredients and send the byproducts into waste streams to landfill. This increases the load on landfills and decreases the available products for animal food feed, thereby increasing the cost. So my question is, will the FDA performance an environmental impact analysis before the final rule?

And again, I want to ask this as well. Can FDA quantify the benefits of their proposal?

Mr. {Taylor.} Sure. So with respect to the environmental impact statement, we are doing an environmental impact statement on the produce rule, and so that will accompany and parallel the rulemaking process and we will have that before the final rule. But on the specific issue, it is not our intent, and we are going to work hard based upon input we received from the community to disrupt these established practices of byproducts of human food production going into the animal feed system. I mean, that is an important part for reasons you have recited of our food system, so it is not our intent and we don't think from a food safety standpoint that would be necessary or appropriate.

So this is the kind of issue that arises during the rulemaking where we get comments, and I think we will work to harmonize the produce and preventive control rules to prevent outcomes that just don't make common sense. I mean, we are guided by common sense here, and I think this is an issue that is very manageable within the FSMA regime.

Mr. {Bilirakis.} Okay. Very good. Thank you. I will move on to the next question.

With regard to cybersecurity, the proposed rule would require all mandatory records to be made promptly available to the FDA upon oral or written request. Is that correct?

Mr. {Taylor.} Yes.

Mr. {Bilirakis.} Okay. If the FDA requires these records to be submitted electronically and reviewed remotely, how will the FDA validate that the requests are coming from authorized representatives, and more importantly, can you guarantee that the system will be safe from hackers or leaks?

Mr. {Taylor.} So the first point is, it is a work in progress and we need to work with the industry to figure out how we exchange information in a way that is most efficient for our collective purpose of protecting food safety, and so this is something we have to do in dialog with the industry including with respect to electronic transfer of records.

To the extent that records are transferred electronically, we absolutely have to protect the confidentiality of records that are confidential business information, and we have a lot of experience doing that with

conventional records within our food program. There is a lot of experience elsewhere in FDA with electronic submission of data and the drug approval system. So I commit to you, there is no lack of sensitivity to the importance of protecting confidentiality of data. We have a lot of experience doing it, and it is something we will work with the industry to be sure we do right in this context as well.

Mr. {Bilirakis.} Thank you. My last question, Mr. Taylor, Florida has a significant number of beekeepers, as do other States. The beekeepers and honey production industry along with others have been victims of various illegal trade schemes perpetrated mostly by Chinese exporters. As a result of these trade challenges, a lot of adulterated products such as honey have entered the United States undetected. While imports are the responsibility of Customers and Border Protection, I understand that, once adulterated products enter into the stream of the U.S. commerce, it becomes the responsibility of FDA. Is that correct?

Mr. {Taylor.} That is correct.

Mr. {Bilirakis.} Okay. I would like to know what FDA is doing to combat economically motivated adulteration, FDA's

proposed rule on mitigation strategies to protect food against intentional adulteration to not include economically motivated adulteration within that rule and FDA will address it under a separate regulatory scheme. My question is, could you explain to me how FSMA changes FDA's enforcement authority with respect to economic adulteration and how it will improve FDA's enforcement over economically adulterated products such as honey?

Mr. {Taylor.} Good but complicated question. We will be addressing intentional adulteration for economic purposes in the preventive controls rule. It is a challenge to do that, because in that preventive controls framework, we don't want to require the processor to control that which can't be anticipated, whether it is reasonably likely to occur or probable to occur, regardless of the language you use. We have got to sort of focus what we expect of processors. So we had the melamine in pet food problem a number of years. It was imports from China. You know, that sort of intentional adulteration for economic purposes where you have got a past history of that problem occurring we think can be addressed through the preventive controls rule, but there is

a whole array of economic adulteration issues that are going to have be addressable through other means as a practical manner, and so we do provide guidance about what is appropriate in certain products. We take limited enforcement action within our resources. If it not a safety issue, it necessarily ranks lower in our priorities in terms of deploying our inspection and enforcement responses. But there are things we can do and have done, and we know the concerns in the honey industry and we have had dialog, and we look forward to working further.

Mr. {Bilirakis.} Just a follow-up, has FDA, is there a national standard, have they created a national standard as far as determining whether there is adulteration? If they have not, why haven't they?

Mr. {Taylor.} Well, there is not a national standard of identity that I think some people have asked us to establish that we have not done to date. There are standards and we have acted on if they are illegal pesticide residues or antibiotic residues, which sometimes happen in honey. We have taken action. We can take action under current law. We don't need any new laws or regulations to take action there.

It is more a matter of being able to detect these and invest resources to do the enforcement actions.

Mr. {Bilirakis.} Are in favor of creating a national standard?

Mr. {Taylor.} I think in concept, we see the usefulness of it. Frankly, it is a priority and resource challenge for us, and so we are looking at other ways to try to address this and again welcome working with the industry.

Mr. {Bilirakis.} I really appreciate it. Thanks for the testimony.

Mr. {Pitts.} The Chair thanks the gentleman.

Mr. {Bilirakis.} I yield back. Thank you.

Mr. {Pitts.} The Chair now recognizes the gentlelady from North Carolina, Ms. Ellmers, 5 minutes for questions.

Mrs. {Ellmers.} Thank you, Mr. Chairman, and thank you, Mr. Taylor, for being with us today.

I have a question about, as the rules are being implemented and the scope and the breadth of the rules, to me it is foreseeable that there may be some discrepancies, and I am concerned, and I hope you can expand on the process that can take place if a grower or producer is basically disputing

or disagrees with inspectors' conclusions or the interpretation of the rules, will the FDA provide a centralized timely mechanism for those growers or processors to appeal the FDA? I don't even know. It may not have even gotten that far yet.

Mr. {Taylor.} Well, we are not to the point where we have rules that we are enforcing but we are very sensitive to the fact that in the produce arena, we are regulating on farms in a way we haven't done before, and so we know we have to be sure our people are especially trained to understand and work in the farm environment, and we have to be very careful, particularly in the early years, that we understand what the expectations are, we have communicated that to growers, and then we make consistent decisions when we do see problems, and so there needs to be a process to connect that person who is on the farm with the subject matter experts and others who can be sure we make good, consistent decisions. The Commissioner announced earlier this week some major changes in the way we work internally within FDA to link, you know, our headquarter centers and decision makers with our field force in a much more vertically integrated way to

address this very issue of, do we have the right training, the right oversight and making the right, consistent decisions. So it is something we are very sensitive to as we look forward to implementing the produce rules.

Mrs. {Ellmers.} Well, do you know, and are there plans for basic comprehensive or directive as far as an appeal process?

Mr. {Taylor.} Sure. We already have processes in the chain of command through our field organization but we think produce is going to require some special vehicles. Again, we are going to be implementing these produce rules in close collaboration with States, and in fact, we envision that it is the State agencies that would be the primary frontline interface with growers. We expect to be on farms actually to a very limited extent. We don't have the resources, and we think that the States have real advantages in their local knowledge and expertise. So we need to work out with our State partners. We met with the National Association of State Departments of Agriculture just earlier this week and we are working hard with them to figure out how we will be prepared to partner with them to do this work, so there is a

lot of work to do to put this implementing system in place.

Mrs. {Ellmers.} So you do foresee it as a partnership rather than a jurisdictional issue? Because I know we have run into that problem before.

Mr. {Taylor.} It has to be. I mean, Congress has mandated that we have a national integrated food safety system, has said that we should work with State agencies on produce oversight in particular. We are working hard to build that system. That is the only way we will be successful, we think.

Mrs. {Ellmers.} Thank you, Mr. Taylor. I yield back the remainder of my time.

Mr. {Pitts.} The Chair thanks the gentlelady and now recognizes the gentleman from Kentucky, Mr. Guthrie, 5 minutes for questions.

Mr. {Guthrie.} Thank you, Mr. Chairman, and thank you for coming today.

I have a specific question that has been brought up in my peculiar--not peculiar to my district, but my understanding is that the proposed rule would apply to facilities that manufacture, process, pack or even hold

animal food so they would be required to register it as a food facility under 415 of the Food, Drug, and Cosmetic Act if they fit that category, my understanding is, so the question is distilleries. I know alcohol is exempted from this particular section but the byproducts, so they are not manufacturing food but they take the corn, they take the mash and do their formula and distill off the alcohol and then the remaining is actually good protein corn because they use the best corn in the world, and so farmers do buy that. And so the question is, would a distillery that sells their--or any, you can do an ethanol plant, you can sell their byproduct as animal food required to register under 415? And that is a concern they have.

Mr. {Taylor.} Yes, the registration requirement--I am turning to my colleague because I don't want to give you the wrong answer, and we know this is an issue in the FSMA implementation, but the registration requirement was actually established as a result of the Bioterrorism Act of 2002 and regulations FDA issued back then, but it is significant for FSMA because the requirement to implement preventive controls applies to firms that are required to register under the

Bioterrorism Act, and so there is a lot of interaction there and complexity, and frankly, I will have to get back to you on whether the current provisions of our registration requirements apply to the distillery that is producing the byproduct that is going to animal feed.

Mr. {Guthrie.} Yes, they are selling the byproduct instead of to discard it.

Mr. {Taylor.} Understood. But again, I think it is an issue that has come up in the FSMA rulemaking: how does the preventive control regime for animal feed apply to just that sort of situation. So this is an issue we will have to resolve in a practical way and again, the whole goal here is to achieve the food safety goal without imposing regulation just for regulation's sake, so we will have to figure out what the right practical answer is to be sure that the animal feed safety issue is being addressed in the most practical way.

Mr. {Guthrie.} Yes, I know it is very specific, so your getting back to me is a fair very point.

Mr. {Taylor.} Yes, sir, we will do that.

Mr. {Guthrie.} Thank you.

Mr. {Pitts.} The Chair thanks the gentleman and now recognizes the gentleman from Georgia, Dr. Gingrey, 5 minutes for questions.

Dr. {Gingrey.} Mr. Chairman, thank you very much for holding today's hearing. I would like to welcome our witness, Mr. Michael Taylor, from the FDA.

Mr. Chairman, I understand that our witness served yesterday as a panelist at one of the sessions of the 2014 National Association of State Departments of Agriculture winter policy conference in Reston, Virginia, and the topic was very similar to what we are discussing here at this hearing.

During the Q&A portion of that session, my home State of Georgia Commissioner of Agriculture Mr. Gary Black pursued a line of questioning where he felt he received incomplete answers. I think it was just a lack of time, and I would like simply to follow up on that line of questioning, Mr. Taylor, if you don't mind.

When do you expect the produce and preventive control rules to be finalized?

Mr. {Taylor.} No later, based upon the current court

order, than the end of June 2015. That is our current requirement legally, and we are working to meet that.

Dr. {Gingrey.} At the end of 2015?

Mr. {Taylor.} End of June 2015. June 30, 2015, is the current court deadline.

Dr. {Gingrey.} June 30, 2015, not the end of 2015. All right. Now, these are kind of yes or no questions, and we can go through them pretty quickly.

Mr. {Taylor.} Yes, sir.

Dr. {Gingrey.} Is the intent of the Food Safety Modernization Act to ensure enhanced safety of all produce, both imported and domestic, for American consumers?

Mr. {Taylor.} Yes.

Dr. {Gingrey.} Would you care to speculate what weight the law places on imports versus domestic produce production? Is it fair to say that it is 25 percent import versus 75 percent domestic, or is it equal?

Mr. {Taylor.} Well, I think it is the same goal. We need to have the same assurances about the safety of imported food that we have about domestic food. When I think about where the innovative breakthroughs and real shifts from where

we have been historically in regulation are coming. The import system is very much novel. You know, we have experience with preventive controls in processing facilities in this country through meal and poultry HACCP systems, what we have done for seafood, but it is a big, new departure to hold importers accountable for managing foreign supply chains and to have FDA mandated to be much more present overseas. So imports are a big focus of the law. I would--

Dr. {Gingrey.} Excuse me, because I have to watch my time, but really again, yes or no, is it correct that the current proposed rule for produce is focused on domestic production?

Mr. {Taylor.} No, that is not correct. Those rules will apply to domestic and foreign growers who are shipping food to the United States.

Dr. {Gingrey.} When do you plan to offer a rule on imports and will that rule mirror the proposed rule for domestic production with respect to content and ultimate impact?

Mr. {Taylor.} So the proposed rule on produce safety applies to foreign and domestic growers. The proposal we

published in the summer of last year on foreign supplier verification is the central rule mandated by FSMA for strengthening oversight of imports because that--

Dr. {Gingrey.} Let me cut right to the chase here. Can you assure farmers in Georgia and across the country that they will not be placed at a competitive disadvantage with importers once both the domestic and import rules are finalized?

Mr. {Taylor.} That is absolutely our goal, and if we get the resources to implement the import provisions of this law, we can achieve that goal.

Dr. {Gingrey.} Well, that is reassuring.

Mr. Taylor, last question, but it is a longer one. Are you familiar with what has been coined as the BASE--this is an acronym--approach for produce safety under the Food Safety Modernization Act that has been promoted by my State's department of agriculture? Are you familiar with that?

Mr. {Taylor.} Not the acronym but--

Dr. {Gingrey.} B-A-S-E?

Mr. {Taylor.} Yes.

Dr. {Gingrey.} BASE puts States in the best position to

efficiently drive the program under federal regulations, thereby keeping hopefully the FDA off of American farms. Do you believe that this approach has merit?

Mr. {Taylor.} Yes, and we are working--it is not that we will never be on farms but as I said earlier, we want to partner with State agriculture departments, health departments, those who are involved in produce safety at the State level to be the frontline, the primary frontline presence working with growers, overseeing growers and verifying compliance. That is absolutely the system that we are working to develop.

Dr. {Gingrey.} Well, again, that is quite reassuring, and as I conclude, for those that might not know, BASE, the B represents borders between countries, where federal involvement in produce safety begins at the borders and the ports of entry. A represents the correct role for the FDA is to audit State programs. S represents standards set across the entire country, and lastly, E represents, and I think you just said that, Mr. Taylor, represents education for State regulators. BASE puts States in the best position to efficiently drive the program under federal regulations,

thereby hopefully keeping the FDA off of American farms.

So I am very pleased with your response, and I see my time has elapsed so I will yield back.

Mr. {Taylor.} Thank you.

Dr. {Gingrey.} Thank you, Mr. Taylor.

Mr. {Pitts.} The Chair thanks the gentleman. That concludes the questions of the members who are present. There are other questions that members may have that we will send to you. I hope you will respond promptly. I hope you understand, we have a couple of subcommittee hearings going at the same time so members have been in and out.

Mr. {Taylor.} Yes, sir.

Mr. {Pitts.} Thank you. And I remind members that they have 10 business days to submit questions for the record. They should submit their questions by the close of business on Thursday, February 20th.

Very important hearing, very important issues, very informative. Thank you very much, Mr. Taylor.

Mr. {Taylor.} Thank you, Mr. Chairman.

Mr. {Pitts.} We look forward to continuing to work with you.

Without objection, the subcommittee is adjourned. Thank you again.

[Whereupon, at 11:49 a.m., the subcommittee was adjourned.]